REMARKS

A. Status of Claims

Claims 1-4, 6, 11, 74-95, and 97-108 are pending.

Claim 3 has been amended without prejudice or admission. Support for this amendment can be found, e.g., in paragraph [0032] of the application as filed.

Claim 89 has been amended without prejudice or admission to correct a typographical error.

It is respectfully submitted that no new matter has been added by virtue of these amendments.

Claims 3, 6, 74-80, 82, 84, 86, 88, 90-95, 97-99, 99, 100, and 102-108 are encompassed by the elected invention.

B. Substance of Interview

In accordance with the provisions of 37 CFR 1.133, Applicant herein makes of record the substance of the telephonic interview conducted on March 15, 2011, between Applicant's attorney Oleg Ioselevich and Examiner Micah Paul Young.

During the interview, the amendments and arguments made in the response filed on January 14, 2011 were discussed.

Applicant thanks the Examiner for granting the interview, and respectfully requests that the substance of interview be made of record.

C. Claim Rejections- 35 U.S.C. § 103

Claims 3, 6, 74-80, 82, 84, 86, 88, 90-95, 97-99, 99, 100, and 102-108 were rejected under 35 U.S.C. § 103(a) over the combination of U.S. Patent No. 5,419,920 to Masson et al. ("the '920 patent") and U.S. Patent No. 5,494,681 to Cuca et al. ("the '681 patent").

The rejection is respectfully traversed.

Independent claims 3, 6, 80, and 84 are directed to methods for providing for the identification of a pharmaceutical dosage forms.

The Examiner states that "[w]hat is lacking in the '920 patent is a disclosure of a specific dosage form and drug." Office Action, page 3.

While Applicant agrees with this statement, the Examiner should note that the '920 patent also lacks a disclosure of any pharmaceutical dosage forms, any suggestion that the "markers" described therein are suitable for incorporation into pharmaceutical dosage forms, and the disclosure of any methods for providing for identification of pharmaceutical dosage forms.

The '920 patent therefore fails to teach or suggest any reason to a person of ordinary skill in the pharmaceutical arts to use the method described therein to impart a scent or scent profile to a pharmaceutical dosage form comprising an active agent during manufacture of the dosage form so as to authenticate the identity or source of the dosage form as recited in the present claims.

There is also no connection between the '920 patent and the '681 patent. The '920 patent is neither concerned nor is not reasonably pertinent to the taste-masked pharmaceutical materials described in the '681 patent. The skilled person would therefore not have had any reasons to combine the '920 patent and the '681 patent, let alone use the method described in the '920 patent to impart a scent or scent profile to a pharmaceutical dosage form comprising an active agent during manufacture of the dosage form to determine the identity or source of the dosage form as recited in the present claims.

The Examiner states on page 3 of the Office Action that "[i]t would have been obvious to track and identify the dosage form of the '681 patent by the method of the '920 patent in order to keep track of schedule 1 substances from a distance."

Applicant respectfully disagrees with the Examiner's assertion. The cited references do not use the term "schedule 1 substance" and do not describe a need to keep track of schedule 1 substances from a distance. There is also no disclosure in the cited references of using any scent to identify any pharmaceutical dosage form. Applicant therefore submits that it would not have been obvious to track and identify the dosage form of the '681 patent by the method of the '920 patent in order to keep track of schedule 1 substances from a distance.

The Examiner states on page 3 of the Office Action that "providing a dosage form with a scent, such as orange, etc. in the '681 patent would 'allow' (render capable) the dosage form to be authenticated via smell, thus meeting the allowing step recited in the instant claims." The Examiner further states on page 4 of the Office Action that "the '681 patent alone meets the limitations of 'allowing for an authentication of the dosage form' by merely adding the scent."

In response, Applicant respectfully submits that the Examiner's assertions are not based on the disclosure of the '681 patent, as there is no teaching or suggestion in the '681 patent to use the purported "scents" to determine the identity or source of the dosage forms disclosed therein. The purported "scents" in the '681 patent are "[f]lavors which may optionally be added to the delivery system" of the '681 patent. Applicant respectfully submits that these statements are not based on the disclosure of the '681 patent. Rather, they are based on the information gleaned from the present specification.

Applicant further submits that disclosure of the purported scents in the '681 patent does not teach or suggest the "allowing" step recited in the present claims (i.e., "allowing for an authentication of the dosage form"). Applicant respectfully notes that present claims 3, 6 and 84 specify that "allowing for an authentication of the dosage form" is by a step of "associating the scent or scent profile" with the identity or source of the dosage form. Present claim 80 recites

that "allowing for an authentication of the dosage form" is by a step of "imparting a scent or scent profile useful to determine the identity or source of the dosage form." These specific steps recited after the term "allowing" in present claims 3, 6, 80 and 84 are not taught or suggested by the '681 patent.

The Examiner further states on page 3 of the Office Action: "Regarding the differentiating between batches, it would be obvious to apply different flavors to different batches in order to tell them apart after manufacture." Office Action, page 3. Applicants again cannot find support for this statement anywhere in the '681 patent. There is simply no disclosure in the '681 patent of varying flavors to identify different batches. Accordingly, Applicant again submits that this statement is not based on the disclosure of the '681 patent. Rather, it is based on the information gleaned from Applicant's disclosure.

In response to the Examiner's statement on page 3 of the Office Action that "[v]arying the scent profile with different batches would allow the artisan of ordinary skill to tell the difference between codeine, morphine and other opioid analgesics," Applicant respectfully notes that the "different batches" of the dosage forms recited in claims 75 and 78 will contain the same active agent, rather than different active agents, as the claims recite "the scent or scent profile is detectably varied between different batches **of the dosage form**." (emphasis added).

In response to the Examiner's statement that "[t]he '920 patent establishes the level of skill in the art regarding imparting a traceable scent to a polymeric film," Applicant respectfully submits that the '920 patent is not concerned with the pharmaceutical arts and that there is no indication in the '920 patent that the polymeric films disclosed therein are pharmaceutically acceptable polymers.

In response to the Examiner's statement on page 4 of the Office Action that "[i]t would have been obvious to tract [sic; track] the scented dosage forms of the '681 patent by the method of the '920 patent in order to prevent theft and reduce counterfeiting," Applicant respectfully reiterates that there is also no disclosure in the cited references to use any scent to identify any pharmaceutical dosage form, let alone using the scent to determine "when and/or where the

pharmaceutical dosage form was manufactured, bottled or packaged" as recited in amended claim 3. The problems of theft and counterfeiting of pharmaceutical dosage forms is also not described in any of the cited references.

For the foregoing reasons, the combination of the cited references does not provide any reason to a person of ordinary skill in the pharmaceutical arts to impart a scent or scent profile to a pharmaceutical dosage form comprising an active agent during manufacture of the dosage form to authenticate the identity or source of the dosage form as recited in the instant claims. Furthermore, the combination of the cited references do not teach or suggest the use of a method to impart a scent or scent profile to a pharmaceutical dosage form comprising an active agent during manufacture of the dosage form to determine the identity or source of the dosage form as recited in the present claims.

Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

An allowance of the present application is earnestly solicited. According to currently recommended Patent Office policy, the Examiner is specifically authorized to contact the undersigned by telephone in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
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